PART IV: INSTRUCTIONS FOR NON-COMPETING CONTINUATION CCSG APPLICATIONS

A. INTRODUCTION

These instructions supplement those provided in the "Application for Continuation of a Public Health Service Grant" PHS 2590 (rev.5/95) package for the non-competing continuation applications. Per PHS policy, a continuation application and progress report must be submitted for each continuing year of the grant **two months** before the beginning date of the next budget period.

The information provided in the Cancer Center Support Grant (CCSG) continuation applications serves as a basis for continued support, and is used to monitor scientific and programmatic progress and to ensure that public funds are used appropriately within all NCI/NIH/PHS guidelines and regulations. The narrative portions of applications are used by the NCI staff for showing the importance and uniqueness of cancer centers to within the Department of Health and Human Services, as well as to the public and to Congress.

B. FORMAT: Note that the format below parallels wherever possible the format for competing applications (See Part III of these Interim Guidelines).

B.1 Face Page: Complete the Face Page as described in the PHS 2590 application package. The requested total costs for the next budget period should not exceed the recommended total costs shown on the latest Notice of Grant Award.

B.2 Table of Contents: Provide headings with correct page references.

B.3 Director's Scientific Overview:

B.3.1 Scientific Progress and Plans:

Highlight the most significant **published** scientific accomplishments that you believe should be considered by the NCI when reporting to its advisory groups and to Congress. Discuss next year's plans for developing any new scientific directions and/or taking advantage of new research opportunities. Broadly discuss progress over the current year, noting any important changes in key personnel, scientific Programs, shared resources and/or institutional commitments that have enhanced the scientific capability and productivity of the center.

B.3.2 Scientific Accomplishments of High Congressional and Public Interest: Areas of particular interest to Congress and the public include breast cancer, prostate cancer, ovarian cancer, cervical cancer, AIDS-related malignancies, cancer vaccine development, gene therapy, cancer genomics research, genetic/heritable cancer risk factors, environmental risk factors and high incidence cancers in minority and underserved populations. If any of the most significant accomplishments

reported in B.3.1 above are in one of these areas of high visibility, please prepare **in lay language** a paragraph that describes the nature of the discovery and its potential significance to cancer prevention, diagnosis, and/or treatment, so it can be used easily to illustrate the special contributions of NCI cancer centers in fighting cancer.

B.4 Standard Cancer Center Information

Information to be Provided Annually (See Attachment):

Summary 1:   Part A - Research Programs, Leaders and Codes
                     Part C - Shared Resources, Resource Directors, and Categories

Summary 2:   Existing Funded Projects

Summary 4:   Clinical Research Protocols

B.5 Progress Reports and Budget Requests for All CCSG Categories: Using the PHS 2590 Form, provide a separate detailed budget for each category (e.g., senior leaders, program leaders, developmental funds, individual resources, etc.) in the **same sequence** used in your competing application. Provide accompanying explanations and/or justifications **only** for changes in each budget (i.e., as they relate to the peer review recommended levels) whether or not they require NCI approval. For explanation and clarification in how to deal with budget requests, refer to Section C below. **Brief** narrative progress reports and plans should accompany each budget request as follows:

B.5.1 Research Programs: For each Program, describe its scientific progress and achievements in the current year emphasizing the **most significant published scientific accomplishments**, and indicate how the **center has facilitated** these accomplishments. Please highlight those accomplishments of particular importance to cancer but also include any important scientific accomplishments that are not obviously related to cancer. In addition, discuss plans for the development of new scientific, capabilities, directions and opportunities, if any, and their potential impact on the goals and objectives of the Program. Include a selected list of Program-related publications of the current year, highlighting those that illustrate inter- and intra-programmatic collaborations.

B.5.2 Program Planning and Evaluation: Describe how the planning and evaluation activities of the center helped the center achieve its scientific goals and objectives in the current year and how they will be used to enhance the strategic development of the center's scientific objectives in the next year.

B.5.3 Developmental Funds: Describe how the funds in various sub-categories of developmental budget were used in the current year, highlighting, for each sub-category, those activities that benefitted and enhanced the strategic development of the center's scientific

capability. Describe how developmental funds will be used in each sub-category in the next year.

B.5.4   Shared Resources: For each shared resource, report on any major changes made in the resource's scientific and/or technical capabilities and usage, including those planned for the next year, and briefly discuss the importance of these changes on the scientific productivity of the research activities it serves.

B.5.5   Protocol Specific Research: Describe the status of Pilot/Phase I research protocols supported by these funds in the current year, and indicate which protocols have led to the next level of studies (e.g., Phase II) and/or have received external peer reviewed support.

C.   GENERAL CONSIDERATIONS FOR ALL BUDGET REQUESTS AND JUSTIFICATIONS

In general, all budgets should be prepared according to the NIH guidelines contained within the PHS 2590 Form. Budget explanations and justifications are required **only** when the changes in key personnel, percent efforts for key personnel and/or budget levels diverge significantly from that which were reviewed and recommended by peer reviewers. The factors to consider in preparing budgets are as follows:

C.1   Rebudgeting: The center has flexibility to make **cumulative** (i.e., over the entire project period) increases to any budget category up to 25% of the peer reviewed recommended levels without prior NCI approval as long as these were rated excellent or better by peer reviewers. However, **all** significant rebudgeting between categories requires a budget explanation or justification in the application.   While **cumulative** rebudgeting greater than 25% into categories rated better than excellent OR any rebudgeting into categories rated less than excellent by peers **requires NCI approval**, centers are encouraged to include the appropriate rationale and documentation along with the request (See Part I of these Interim Guidelines, Section 10.2). In order to expedite this process, you are encouraged to discuss with your NCI ProgramDirector any anticipated rebudgeting that may require NCI prior approval before submitting your non-competing continuation application.

C.2   Changes in Personnel:

C.2.1   Changes in percent effort of **key personnel:** By NIH policy changes greater than 25% or more in the level of effort of **key personnel** (e.g., center director, senior leaders, program leaders, resource leaders, senior administrators and staff investigators) should be carefully justified.

C.2.2   Substitutions of/New **key personnel:** Substitutions of key personnel should be fully justified and should be accompanied by their biographical sketches and/or curriculum vitae. These kinds of substitutions **require NCI approval**. If a change involves a new position for key personnel (i.e., a position not previously peer reviewed and approved), see section C.3 below.

C.2.3 Changes in percent effort and substitutions of **non-key** personnel should be noted briefly.

C.3 Special Requests

The following kinds of special requests **require NCI approval** and should be submitted **separately** from the non-competing renewal application:

1. The creation of a **new** budget category (e.g., a new resource) or new key personnel positions (e.g., a new senior leader, a new staff investigator) that would normally be subject to peer review evaluation from within the committed levels on the Award Statement. Substitutions of key personnel in positions that have been peer reviewed should be highlighted and justified in the text of the non-competing renewal application (See C.2.2).

2. Any requests for additional funds over the committed levels on the Award Statement. Applicants should understand that requests for additional funds are only approved and funded under exceptional circumstances.

3. Requests for carryover of funds from one budget period to the next.

All Special Requests should be in the form of a narrative justification **co-signed** by the center director and a business official of the institution. Attach detailed budget pages, as provided in the PHS Form 2590. These requests should be submitted to the Grants Management Specialist with a copy to the Program Director for your grant.